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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/425,501	10/22/1999	ROBERT MARK	GNN-005	9642

25291 7590 02/05/2003

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MADISON, NJ 07940

EXAMINER
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CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 02/05/2003

29

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/425,501

Applicant(s)

MARK ET AL.

Examiner

Suryaprabha Chunduru

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 5-13, 16-21, 43, 44 and 49-65 is/are pending in the application.
- 4a) Of the above claim(s) 5-13 and 16-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 43-44, 49-65 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 23.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. Applicants' response to the office action (Paper No. 22) filed on November 4, 2002 has been entered and considered.
2. The IDS (Paper No. 23) filed on November 4, 2002 has been entered and considered.

**Response to arguments**

3. Applicants' response to the office action (Paper No. 22) is fully considered and found persuasive in part.
4. The Declaration submitted under 37 C.F.R. 1.132 has been considered and found not persuasive. The Declaration shows citations of NCBI Blast search for an isolated nucleic acid and amino acid sequence homology (99-100%) obtained from a mouse clone. The NCBI blast search exhibits are fully considered. As per the "85% language", the declaration is found persuasive, however the showings do not commensurate with the newly amended claims drawn to human isolated nucleic acid and corresponding amino acid sequence, the disclosure of Nagase et al. is from a human clone and hence the disclosure of Nagase et al. is operable in the instant context. MPEP 2121.02 notes "One of ordinary skill in the art must be able to make or synthesize" regarding operativeness of products. Here, Nagase et al. in fact synthesizes the nucleic acid, and an ordinary practitioner in molecular biology could synthesize any known sequence using a selection from any of a garden variety of extremely well known methods ranging from simple chemical synthesis to ligation to PCR amplification with 100% expectation of success.
5. With respect to the rejection made in the previous office action under 35 USC 102(b), Applicants' amendment and arguments have been fully considered and found not persuasive.

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Applicants argue that the prior art of the record (Nagase et al.) does not provide any enablement for the isolated nucleic acid, which has 100% homology with the instant SEQ ID Nos. 1, and 2. This argument is fully considered and found not persuasive because enablement issue is not relevant in the present context. It is concerned with whether the reference is operable or not. The prior art teaches the nucleotide sequence which is within the public domain. As stated in MPEP 2121.02, "ONE OF ORDINARY SKILL IN THE ART MUST BE ABLE TO MAKE OR SYNTHESIZE", one could be able to chemically synthesize the sequence, ligate and amplify the product based on the prior art information and is can make the compound operable. MPEP 2121.02 further states "a reference is presumed operable until applicant provides facts rebutting the presumption of operability. In re Sasse, 629 F.2d 675, 207 USPQ 107 (CCPA 1980). Therefore, applicant must provide evidence showing that a process for making was not known at the time of the invention. The citations to the utility guidelines is irrelevant because the prior art is not required to be useful to anticipate. The chemical sequence is known in the art as disclosed by Nagase et al. Thus the reference is operable under ordinary circumstances. Therefore, the rejection is maintained herein. New claims 62-65 are also rejected herein under 35 USC 102(b) as anticipated by Nagase et al. because the said isolated nucleic acid of Nagase et al. meets the limitations regarding Bcl-xL binding properties as discussed above and homology greater than 91% to the said nucleic acid (see sequence alignment provided in the previous office action).

6. With respect to the rejection made in the previous office action under 35 USC 112 first paragraph, Applicants' arguments (Paper No. 22) are considered, but found persuasive in part. Applicants' arguments and amendment of the instant claim 49, with regards to homology is fully considered and found persuasive. The objection to the "85% language" is withdrawn herein to

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the instant claim 49, however for hybridizable fragments and position of binding activity of said isolated nucleic acid under hybridizable conditions, the argument is not convincing. By permutation and combination, there would be over several thousand possible fragments, if not millions as discussed in the earlier office action. With regards to the arguments to the identity of biological function in the said nucleotide or peptide of SEQ ID Nos. 1 and 2, it is not sufficient enough to identify where in the sequence the biological function resides or position of amino acids responsible for the biological activity. Applicants' suggestion to note the specification for the teaching of structure / function relationship is fully considered, but the limitation is not found in the claims. Specification cannot be read into the claims. Therefore, the rejection is maintained herein. New claims 62-65 are also rejected herein under 35 USC 112, first paragraph, since the new claims 62-65 are dependent on the independent claim 52, which was rejected in the previous office action and the rejection is maintained herein.

### ***Conclusion***

No claims are allowable.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the


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examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Suryaprabha Chunduru  
January 31, 2003

  
JEFFREY FREDMAN  
PRIMARY EXAMINER